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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,467	08/13/2001	Spiridon Spireas	MPCI-0033	6452

7590 01/15/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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20

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 11/27/03
- ☐ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 82-105 is/are pending in the application.
- ☐ Of the above, claim(s) 92, 93 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 82-91, 94-105 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 19
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Claims 82-91, 94, 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 82 "susceptible" is vague; under what conditions?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-91, 94-45 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/28255.

WO 98/255 teaches pretreating gabapentin hydrochloride in ethanol and recovering gabapentin hydrochloride (claims 10, 11).

~~WO 98/255 also teaches –~~

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 96-105 are rejected under 35 U.S.C. 102(e) as being anticipated by Singer et al '509.

Singer et al '509 teach stable gabapentin with greater than 20 ppm chloride (abstract). Treatment with dry isopropanol followed by drying is disclosed (example 1). Starch is specified (column 3 line 29). Applicants point to water, however, a reference is not limited to its examples.

Claims 100, 103-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 100 "mineral acid" has no antecedent in claim 96. In claims 103-106 "removing step" has no antecedent in claim 96.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 82-91, 94-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vilkov (US Patent No. 6,294,198 B1).

Vilkov teaches gabapentin processing with ethanol (title, abstract, column 5, lines 35-37), starch (column 6, line 20), and calcium stearate (column 6, line 14). A tablet is specified (abstract).

As to the claimed chloride, gabapentin is available as a chloride salt (see Satzinger et al. US Patent No. 4,087,544, column 2, line 10). It is well known in the art that the salt of an organic compound is more soluble than the organic compound itself. It would have been obvious to one of ordinary skill in the art at the time the invention

Art Unit: 1617

was made to use the chloride salt of gabapentin as the active agent in Vilkov to achieve the beneficial effect of a more soluble active. Applicant argues that Vilkov does not teach at least 20-ppm anion. However, the Chloride form of Gabapentin in the obvious composition provides the claimed anion. Applicant also argues that there is no motivation in Vilkov to modify Vilkov. However, the motivation to combine is based on the well-known fact that salts of organic compounds are more soluble in water than the organic compound itself.

Applicants further argue that the prior art teaches away from 20 ppm, citing ^{Aug} ~~apart~~. However, Singer et al '509 does teach ^f greater than 20 ppm.


No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR
December 2, 2003


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500